Chapter 2.3.13. Bovine spongiform encephalopathy

For this chapter, the Bureau of the Code Commission produced two alternative versions, taking into account comments received from Member Countries. Part a) contains a proposed new chapter with a simplified categorisation system while Part b) proposes a revised current chapter.

The Bureau urges Member Countries to examine these two approaches and to send comments to the Central Bureau.

a) New BSE chapter with a simplified categorisation system

Recalling the support from the OIE International Committee at the 72nd General Session for a simplified categorisation system for BSE, the Bureau of the Code Commission drafted a new text reflecting this approach.

The following criteria were the basis for formulating the new text:

i) the recommendations from the *ad hoc* Group meeting of April 2004 for a three category approach.

ii) proposals from Member Countries – the EU, the USA, Australia, New Zealand, Japan, South Africa, Korea and Argentina – for a new approach;

iii) the shift in emphasis agreed by the OIE International Committee towards commodity-specific recommendations;

iv) the linkage between risk assessment outcomes and surveillance, and the ability to be categorised as negligible BSE risk with or without mitigating measures; and

v) the recommendations of the *ad hoc* Group regarding the factors relevant to a risk assessment and the safety of certain commodities.

Articles were consolidated as necessary to address a three category approach but changes to existing recommendations were minimised. In the explanation below, 'current Article' refers to the 2004 edition of the *Terrestrial Code.*

Article 1 was not modified with regard to specific commodities because of the absence of any new scientific information on the risks presented. With the respect to tallow, this approach reflects the position of the BSE *ad hoc* Group. The Bureau understands that the results of an investigation into whether or not the BSE agent may be present in tallow will soon be released. In addition, while the *ad hoc* Group believed that the information available indicated that 'bovine blood and blood by-products' would be safe (subject to stunning being carried out in accordance with the current Article 2.3.13.14), the Bureau awaits further concrete scientific information before making recommendations on their use.

Article 2 was modified, taking into consideration the recommendations of the *ad hoc* Group on the factors important to release and exposure assessments.

A new Article 3 addressing a category named '*negligible BSE risk without mitigating measures'* was drafted by merging current Articles 2.3.13.3 and 2.3.13.4 describing free and provisionally-free categories, and taking into consideration the recommendations of the *ad hoc* Group and

comments received from Member Countries. Recommendations regarding the destruction of progeny were retained for a country or zone/compartment which had reported a case of BSE more than 7 years ago; however, the Bureau was of the view that, in the light of the lack of evidence for vertical transmission, these recommendations should be dispensed with from this article and the new Article 4.

The new Article 4 addressing a category named '*negligible BSE risk with mitigating measures*' incorporates the current Articles 2.3.13.5 and 2.3.13.6 describing minimal and moderate risk categories, and includes the concept of 'high BSE risk' in its recommendations. In this exercise, the Bureau took into consideration the recommendations of the *ad hoc* Group and comments received from Member Countries.

In order to have a single middle category, the Bureau considered it necessary not to differentiate risk levels for commodities on the basis of BSE incidence rate. In this regard, the Bureau agreed with the *ad hoc* Group's proposal that because of the difficulty of estimating accurately the prevalence of BSE infection and the relative lack of importance of prevalence in relation to rendering commodities safe, a broad second category be created with no arbitrary distinctions. Australia recommended an emphasis on risk assessment and disease management rather than on disease incidence in drawing up new categories. The USA also supported a risk-based rather than prevalence-based approach to categorisation. The Bureau considered that this approach did not reduce the importance of surveillance in categorising countries or zones/compartments.

A new Article 5 '*undetermined* BSE *risk*' was created for those countries or zones/compartments which, by not conducting a risk assessment or surveillance, could not be categorised in either of the above categories but which could still trade safely in certain commodities under specified conditions.

In accordance with the proposed 'three category system', the articles dealing with commodities have been redrafted to address the risk posed by the combination of the commodity and the source country or zone/compartment.

A new Article 6 is essentially unchanged from the current Article 2.3.13.8 which dealt with imports from free countries or zones.

A new Article 7 dealing with cattle from a country or zone/compartment posing a negligible BSE risk with mitigating measures resulted from a merger of the existing recommendations in current Articles 2.3.13.10 and 2.3.13.11.

The existing recommendations for the import of cattle from a country or zone with a high BSE risk were incorporated unchanged in new Article 8 addressing cattle from a country or zone/compartment with an undetermined BSE risk.

On the recommendation of the *ad hoc* Group, recommendations for post-mortem inspection were added to new Articles 9, 10 and 11 to address the need to certify to certain tissues having been removed in a manner to avoid contamination.

The new Article 10 is a combination of current Articles 2.3.13.14 and 2.3.13.15. The recommendations regarding the age for the removal of specified risk materials were based on expert advice regarding pathogenesis studies and epidemiological analysis.

The new Article 11 was modified from the current Article 2.3.13.16, taking into account the recommendations of the *ad hoc* Group, and in order to adapt it for Member Countries in which

animal identification and traceability are not required. The Bureau did not believe that such systems would play a significant role in further mitigating any BSE risk posed by the exported commodity.

The recommendation for the removal of the entire intestine was reconsidered, and in view of comments from the USA, Thailand, Taiwan, Korea, Canada and Japan and advice from an expert, the Bureau now proposes that the current Article 2.3.13.18 (new Article 13) be modified to require the exclusion from trade of the distal ileum only.

The substance of the remainder of the articles is unchanged. The Bureau considered that the recommendations in the current Article 2.3.13.22 are substantially incorporated into new Article 2 and proposes deletion of this article.

PROPOSED SIMPLIFIED VERSION

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 1

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the exporting country or zone/compartment:

   a) *milk* and *milk products*;

   b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

   c) hides and skins (excluding hides and skins from the head);

   d) gelatin and collagen prepared exclusively from hides and skins (excluding hides and skins from the head);

   e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

   f) dicalcium phosphate (with no trace of protein or fat).

2) When authorising import or transit of the following *commodities*, *Veterinary Administrations* should require the conditions prescribed in this Chapter relevant to the BSE risk status of the cattle population of the exporting country or zone/compartment:

   a) cattle;

   b) *fresh meat* and *meat products*;

   c) gelatin and collagen prepared from bones or from hides and skins from the head;

   d) tallow and tallow derivatives, other than protein-free tallow as defined above;

e) dicalcium phosphate, other than dicalcium phosphate with no trace of protein or fat.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2

The BSE risk status of the cattle population of a country or zone/compartment can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment (which is reviewed annually), based on Section 1.3 of this *Terrestrial Code*, identifying all potential factors for BSE occurrence and their historic perspective:

a) Release assessment

Release assessment consists of assessing the likelihood that a transmissible spongiform encephalopathy (TSE) agent has been introduced into the cattle population from a pre-existing TSE in the indigenous ruminant population or via the following commodities potentially contaminated with a TSE agent:

i) *meat-and-bone meal* or *greaves* from the indigenous ruminant population;

ii) imported *meat-and-bone meal* or *greaves*;

iii) imported live animals;

iv) imported animal feed and feed ingredients;

v) imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 13 and may have been fed to cattle;

vi) imported products of ruminant origin for *in vivo* use in cattle.

b) Exposure assessment

Exposure assessment consists of assessing the likelihood of exposure of the BSE agent to cattle, through a consideration of the following:

i) the presence or absence of animal TSE agents in the country or zone/compartment and, if present, their prevalence based on the outcomes of surveillance;

ii) prevalence of infection of animals with TSE agents in the country or zone/compartment, including the surveillance and other epidemiological investigations on which the determination is based;

iii) recycling and amplification of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin, or other feed or feed ingredients contaminated with these;

iv) the use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

v) the feeding or not of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants, including measures to prevent cross-contamination of animal feed;

2) on-going awareness programme for veterinarians, farmers, and workers involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases showing clinical signs consistent with BSE in target sub-populations as defined in Articles 3.8.4.2 and 3.8.4.3;

3) the compulsory notification and investigation of all cattle showing clinical signs consistent with BSE;

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4; records of the number and results of investigations should be maintained for at least 7 years;

5) the examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance and monitoring system.

Article 3

Negligible BSE risk without mitigating measures

Commodities from the cattle population of a country or zone/compartment pose a negligible risk of transmitting the BSE agent without the need to apply mitigating measures, should the following conditions be met:

1) a risk assessment, as described in point 1) of Article 2, has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and

EITHER:

a) there has been no *case* of BSE, or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed, and:

i) the criteria in points 2) to 5) of Article 2 have been complied with for at least 7 years; and

ii) it has been demonstrated that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

OR

b) the last indigenous *case* of BSE was reported more than 7 years ago; and

i) the criteria in points 2) to 5) of Article 2 have been complied with for at least 7 years; and

ii) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced for at least 8 years; and

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 4

Negligible BSE risk with mitigating measures

Commodities from the cattle population of a country or zone/compartment pose a negligible risk of transmitting the BSE agent due to the application of additional commodity-specific risk mitigation measures, should the following conditions be met:

1) a risk assessment, as described in point 1) of Article 2, has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) a level of surveillance and monitoring which complies with the requirements of Appendix 3.8.4 is in place, and

EITHER

a) there has been no *case* of BSE or any *case* of BSE has been demonstrated to have been imported and has been completely destroyed; and either:

i) the criteria in points 2) to 5) of Article 2 are complied with, but have not been complied with for 7 years; or

ii) it has not been demonstrated that for at least 8 years *meat-and-bone meal* or *greaves* derived from ruminants has not been fed to ruminants;

OR

b) the last indigenous *case* of BSE was reported more than 7 years ago, the criteria in points 2) to 5) of Article 2 are complied with, and a ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants is effectively enforced, but either:

i) the criteria in points 2) to 5) of Article 2 have not been complied with for 7 years; or

ii) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has not been effectively enforced for 8 years;

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed ;

OR

c) the last indigenous *case* of BSE has been reported less than 7 years ago, and:

i) the criteria in points 2) to 5) of Article 2 have been complied with for at least 7 years;

ii) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced for at least 8 years;

iii) all BSE *cases*, as well as:

- all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

- all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, or

- if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed.

Article 5

Undetermined BSE risk

The cattle population of a country or zone/compartment poses an undetermined BSE risk if it cannot be demonstrated that it meets the requirements of another category.

Article 6

When importing from a country or zone/compartment posing a negligible BSE risk without mitigating measures, *Veterinary Administrations* should require:

<u>for all *commodities* from cattle not listed in point 1) of Article 1</u>

the presentation of an *international veterinary certificate* attesting that the country or zone/compartment complies with the conditions in Article 3.

Article 7

When importing from a country or zone/compartment posing a negligible BSE risk with mitigating measures, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone/compartment complies with the conditions in Article 4;

2) cattle selected for export are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin, and are not exposed cattle as described in point 2) c) iii) of Article 4;

3) in the case of a country or zone/compartment with an indigenous case, cattle selected for export were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants had been effectively enforced.

Article 8

When importing from a country or zone/compartment with an undetermined BSE risk, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

2) all BSE *cases*, as well as:

   a) all the progeny of female *cases*, born within 2 years prior to or after clinical onset of the disease, and

   b) all cattle which, during their first year of life, were reared with the BSE *cases* during their first year of life, and, which investigation showed consumed the same potentially contaminated feed during that period, or

   c) if the results of the investigation are inconclusive, all cattle born in the same herd as, and within 12 months of the birth of, the BSE *cases*,

   if alive in the country or zone/compartment, are permanently identified, and their movements controlled, and when slaughtered or at death, are completely destroyed;

3) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the

dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

b) were born at least 2 years after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants was effectively enforced.

Article 9

When importing from a country or zone/compartment posing a negligible BSE risk without mitigating measures, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone/compartment complies with the conditions in Article 3;

2) ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* or *meat products* originate.

Article 10

When importing from a country or zone/compartment posing a negligible BSE risk with mitigating measures, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone/compartment complies with the conditions in Article 4;

2) ante-mortem and post-mortem inspections were carried out on all cattle from which the *fresh meat* and *meat products* originate;

3) cattle from which the *fresh meat* and *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);

4) the *fresh meat* and *meat products* do not contain:

a) the tissues listed in Article 13,

b) mechanically separated meat from the skull and vertebral column from cattle over 30 months of age,

all of which have been completely removed in a manner to avoid contamination with these tissues.

Article 11

When importing from a country or zone/compartment with an undetermined BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the cattle from which the *fresh meat* and *meat products* originate:
   a) are not suspect or confirmed BSE *cases*;
   b) have not been fed *meat-and-bone meal* or *greaves* for at least 8 years;
   c) were subjected to ante-mortem and post-mortem inspections;
   d) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;
2) the *fresh meat* and *meat products* are derived from deboned meat and do not contain:
   a) the tissues listed in Article 13,
   b) nervous and lymphatic tissues exposed during the deboning process,
   c) mechanically separated meat from the skull and vertebral column,

   all of which have been completely removed in a manner to avoid contamination with these tissues.

Article 12

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from a country or zone/compartment defined in Articles 4 and 5 should not be traded between countries.

Article 13

1) From cattle of any age originating from a country or zone/compartment defined in Articles 4 and 5, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: tonsils and distal ileum, and protein products derived thereof. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle that were at the time of slaughter over 30 months of age originating from a country or zone/compartment defined in Articles 4 and 5, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 14

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones or from hides and skins from the head and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the *commodities* came from:

1) a country or zone/compartment posing a negligible BSE risk without mitigating measures; or

2) a country or zone/compartment posing a negligible BSE risk with mitigating measures; and

   a) skulls and vertebrae (excluding tail vertebrae, and hides and skins from the head) have been excluded;

   b) the bones have been subjected to a process which includes all the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment,

      iv) filtration,

      v) sterilisation at ≥138°C for a minimum of 4 seconds,

      or to an equivalent process in terms of infectivity reduction.

Article 15

Veterinary Administrations of *importing countries* should require:

for tallow and dicalcium phosphate (other than protein-free tallow as defined in Article 1) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a country or zone/compartment posing a negligible BSE risk without mitigating measures, or

2) a country or zone/compartment posing a negligible BSE risk with mitigating measures, and it originates from cattle which have been subjected to ante-mortem and post-mortem inspections for BSE with favourable results and has not been prepared using the tissues listed in point 2 of Article 13.

Article 16

Veterinary Administrations of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 1) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1) they originate from a country or zone/compartment posing a negligible BSE risk without mitigating measures; or

2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.